

# Exhibit D

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

Revised 2016 (Resolution 17)\*

## ACR–SIR–SPR PRACTICE PARAMETER ON INFORMED CONSENT FOR IMAGE-GUIDED PROCEDURES

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### PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

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<sup>1</sup> Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, \_\_\_ N.W.2d \_\_\_ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

Prudent and ethical medical practice requires close communication between the patient and the physician. If the patient is unable to provide consent, the patient's legal representative or, in the case of a minor, the patient's parent(s) or legal guardian, represents the patient in the consent process. The patient or representative and, when appropriate, the patient's family must have every opportunity to understand the treatment or procedure the patient is to receive and its reasonable risks, benefits, and alternatives; to have all questions answered; and to fully consent to the treatment and procedure. The degree of disclosure required for a valid consent varies from state to state, but there are 2 generally recognized legal standards. The first is measured by what a reasonable physician in his or her professional judgment believes is appropriate to disclose to the patient. The degree of disclosure depends on perceptions of the physician in each case. The second legal standard is based on what a reasonable patient would want to know in the same or similar circumstances. It is important for each provider to understand his/her individual state requirements and exercise appropriate disclosure based on those standards.

Informed consent is a process of ongoing dialogue/discussion and is not the simple act of signing a formal document. Consent, even when granted by the patient in writing, may reasonably be withdrawn at any time; hence the need for ongoing dialogue. Consent must be documented in the medical record, and consent forms may serve to document the physician's discussion with the patient. These forms usually contain the patient's or representative's signature authenticating understanding of and consent to the treatments and procedures that will be performed. Another acceptable method of documentation is a physician note in the medical record indicating that the discussion took place and that the consent of the patient was obtained; however, this method is less defensible from a legal standpoint because it is only a one-party affirmation of that consent discussion. Informed consent with appropriate documentation must follow institutional policies and procedures and comply with applicable state law.

When obtaining informed consent, the consent process requires face-to-face discussion of the procedure between the physician or other qualified health care provider and the patient. The same standards apply to obtaining consent from the patient's health care representative or legally appointed guardian except that such consent may be reasonably obtained by telecommunication (see section V.B.7). In the case of a minor, consent should be obtained from the patient's parent(s) or guardian per institutional and/or state guidelines. The consent process should include discussion of the anticipated benefits and potential risks of the procedure, as well as reasonable alternatives to the procedure. The patient or representative should have the opportunity to ask questions and discuss the procedure, and all questions should be addressed. The physician performing the procedure has the final responsibility for assuring that all concerns and questions are addressed satisfactorily. Consent should not be obtained in a coercive manner.

## II. INDICATIONS

Informed consent and appropriate documentation should be obtained for, but not limited to, the following procedures:

1. Invasive diagnostic or therapeutic procedures.
2. Moderate sedation. For further information, see the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [1].

Some minor procedures have a documented low incidence of adverse events (eg, intravenous injection of contrast media). These procedures may be exempted from the need for informed consent, but the decision not to obtain informed consent in these circumstances should be based on state law, institutional policy, departmental policy, and local community practice.

### III. QUALIFICATIONS OF PERSONNEL

The physician or other health care provider who oversees or obtains informed consent should be familiar with the elements of informed consent, as well as all aspects of the procedure being proposed, the risks of the procedure, the expected benefits of the procedure, and reasonable alternatives to the proposed procedure.

### IV. RESPONSIBILITIES OF PERSONNEL

In all cases requiring informed consent, the physician or health care provider performing the procedure or other qualified personnel assisting the physician should talk with the patient or representative, explain the procedure, answer all questions, and arrange for appropriate documentation of informed consent. This documentation might take the form of an executed consent form, videotape, or a note in the patient's medical record.

In institutions where department policy or legal advice based on state law requires informed consent for intravenous injections of contrast agents, ACR policy approves the obtaining of informed consent and injection of the contrast medium by qualified, credentialed technologists and nurses. For more information, see the [ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media](#) [2].

### V. SPECIFICATIONS AND DOCUMENTATION

Informed consent and appropriate documentation must be obtained prior to the initiation of any procedure that is likely to expose the patient to any significant risks and potential complications, except in emergency situations, as described in section V.C.

#### A. Radiation Exposure

When obtaining informed consent for image-guided procedures that may be associated with higher levels of radiation (see Appendix A), an explanation of the likelihood and characteristics of deterministic injury should be included in the consent discussion prior to the procedure [3-6]. Radiation dose may be determined and recorded in many different ways [7-9]. The [ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#) [10], the SIR–CIRSE Guidelines for patient radiation dose management, and the National Council on Radiation Protection & Measurements (NCRP) [5,6,11,12] indicate that when a cumulative air kerma at the reference point exceeds 5 Gy, special follow-up precautions should be instituted. Therefore, when a given procedure can be reasonably anticipated to approach this level (see Appendix A), a discussion of deterministic injury should occur as part of the consent process. Special consideration is required for the pregnant patient regarding fetal exposure (>100 mGy conceptus absorbed dose at early gestational stages) [13-15], and it should generate a discussion of potential effects of radiation exposure to the fetus as part of the consent process.

#### B. Protocol for Informed Consent for Elective Procedures

1. Before the proposed procedure is performed, the following will be explained to the patient or, if the patient is unable to provide consent, to the patient's legal representative:
  - a. The purpose and nature of the procedure or treatment
  - b. The method by which the procedure or treatment will be performed
  - c. The risks, complications, and expected benefits or effects of such procedure or treatment
  - d. The risk of not accepting the procedure or treatment
  - e. Any reasonable alternatives to the procedure or treatment and their most likely risks and benefits
  - f. The right to refuse the procedure or treatment
2. After the above items are explained and the physician or health care provider is satisfied that the patient understands the procedure and its possible consequences, the informed consent is executed and appropriately documented. This is most commonly done by having the patient sign a consent form.

3. The name of the person or his or her designee performing the procedure must appear on the consent form prior to the signature by the patient.
4. Documentation: A copy of the consent form(s) or videotape, if used, should be placed in the medical record. In all other situations a note should appear in the medical record that a discussion was held with the patient and that informed consent was obtained. The note should also include the date and time of the discussion, the content of the discussion, and an evaluation of the patient's understanding and response to information provided. A copy of any written informational materials given to the patient may also be included in the medical record.
5. Since the patient must be able to understand the risks at the time he or she gives consent, medications that affect the sensorium should be kept at a minimum and ideally not given to the patient <4 hours prior to the patient's giving consent. Chronic pain medications are less likely to affect the sensorium. No patient should be deprived of adequate pain control for the purpose of obtaining consent.
6. State statutes should be known and followed with regard to consent of those under legal age within that state. Some states have "emancipated minor" or "mature minor" statutes that may apply.
7. Telephone consent: If consent is sought from the patient's health care representative, legally appointed guardian, or family member who cannot be physically present to sign the consent form before the procedure, informed consent may be obtained by telephone. The discussion should be documented on the consent form with a note that the consent was obtained by telephone. In such cases it is advisable to have the discussion witnessed by a second hospital staff member who signs the form as a witness.

#### C. Protocol for Informed Consent for Emergency Procedures

This protocol defines the scope of the emergency exception to the informed consent requirement when a patient needs immediate medical care and is unable to give informed consent.

1. When a delay in treatment would jeopardize the health of a patient and the patient is unable to give informed consent, an exception to the requirement for obtaining informed consent from the patient is made.
2. If the patient is unable to consent and has a legally authorized representative who is available to consent, the treating physician must obtain the informed consent of the representative.
3. When informed consent cannot be obtained from the patient or from his or her legally authorized representative, the physician treating the patient should determine the immediacy of the need for treatment.
  - a. A physician may provide any treatment or perform any procedure immediately required to prevent serious disability or death or to alleviate great pain and suffering.
  - b. During the course of an operation or a procedure, a physician may perform any procedure that becomes necessary because of a condition discovered or arising during the operation or the procedure that presents an immediate threat to the life or the health of the patient.
4. The emergency exception to the requirement of informed consent does not extend to a conscious, competent adult patient, otherwise able to give his or her own informed consent, who has refused to consent to a treatment or a procedure.
5. The need for immediate treatment is documented in the patient's medical record. Documentation includes all information establishing the nature, immediacy, and magnitude of the problem and the impossibility of obtaining consent under the circumstances. Any consulting physicians should enter their findings and recommendations in the record. All notes should show the date and time that the determinations were made.

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**APPENDIX A**

Procedures that have been associated with substantial radiation dose (Adapted from references [3,4,16])

- Transjugular intrahepatic portosystemic shunt creation
- Embolization (any location, any lesion)
- Stroke therapy
- Biliary drainage
- Visceral angioplasty and/or stent placement
- Stent-graft placement
- Chemoembolization
- Angiography and intervention for gastrointestinal hemorrhage
- Carotid stent placement
- Vertebroplasty
- Radiofrequency cardiac ablation
- Complex placement of cardiac electrophysiology devices
- Percutaneous coronary intervention

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\*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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